IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	**N.P. Van Brunt et al.**	**Examiner:**	**D. D. DeMille**
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Reissue of:	**U.S. Patent No. 6,036,662**		
Title:	**OSCILLATORY CHEST COMPRESSION DEVICE**		

AMENDMENT IN REISSUE APPLICATION UNDER 37 C.F.R. § 1.173

Honorable Commissioner for Patents
Washington, D.C . 20231

Gentlemen:

Please amend the above-identified reissue application as follows:

In the Specification:

Please replace the paragraph at column 1, lines 13-22 with the following paragraph:

Certain respiratory disorders, such as cystic fibrosis, emphysema, asthma, and chronic bronchitis, may cause mucous and other secretions to build up in a person's lungs. It is desirable, and sometimes essential, that the secretion build-up be substantially removed from the lungs to enable improved breathing. For example, [Cystic] <u>cystic</u> fibrosis is a hereditary disease that affects the mucous secreting glands of a person, causing an excessive production of mucous. The mucous fills in the person's lungs and must be reduced daily to prevent infection and enable respiration by the person.

In the Claims:

Please amend the following claim:

1. (Amended) An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber;

a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

a first motor operably connected with the crankshaft;

a continuous air flow generator operably connected with the oscillatory air flow generator;

a first feedback and control means operably connected with the oscillatory air flow generator for maintaining [the] a frequency of the oscillatory air flow generator at a predetermined value; and

a second feedback and control means operably connected with the continuous air flow generator for continuously varying [the] an output pressure of the continuous air flow generator in order to maintain [the] a peak pressure generated by the [positive] continuous air flow generator at a predetermined value.

Please add the following new claims:

13. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber;

a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

a first motor operably connected with the crankshaft;

a positive air flow generator operably connected with the oscillatory air flow generator;

a first feedback and control means operably connected with the oscillatory air flow generator for maintaining a frequency of the oscillatory air flow generator at a predetermined value; and

a second feedback and control means operably connected with the positive air flow generator for continuously varying a output pressure of the positive air flow generator in order to maintain a peak pressure generated by the positive air flow generator at a predetermined value.

14. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber;

a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

a first motor operably connected with the crankshaft;

a positive air flow generator operably connected with the oscillatory air flow generator;

a first feedback and control means operably connected with the oscillatory air flow generator for maintaining a frequency of the oscillatory air flow generator at a predetermined value; and

a second feedback and control means operably connected with the positive air flow generator for dynamically adjusting an output pressure of the positive air flow generator in order to maintain a positive pressure generated by the positive air flow generator at a predetermined value.

15. The apparatus of claim 14 wherein the positive pressure is constant.

16. The apparatus of claim 14 wherein the positive pressure is consistent.

17. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber;

a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

a first motor operably connected with the crankshaft;

a positive air flow generator operably connected with the oscillatory air flow generator;

a first feedback and control means operably connected with the oscillatory air flow generator for maintaining a frequency of the oscillatory air flow generator at a predetermined value; and

a second feedback and control means operably connected with the positive air flow generator for maintaining a positive pressure at a predetermined value.

18. The apparatus of claim 17 wherein the positive pressure is maintained at a constant pressure.

19. The apparatus of claim 17 wherein the positive pressure is maintained at a consistent pressure.

20. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber;

a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

a first motor operably connected with the crankshaft;

a positive air flow generator operably connected with the oscillatory air flow generator;

a frequency-compensation feedback system operably connected with the oscillatory air flow generator, wherein the frequency-compensation feedback system maintains a frequency of the oscillatory air flow generator at a predetermined value; and

a pressure-compensation feedback system operably connected with the positive air flow generator, wherein the pressure-compensation feedback system maintains a positive pressure at a predetermined value.

21. The apparatus of claim 20 wherein the positive pressure is maintained at a constant pressure.

22. The apparatus of claim 20 wherein the positive pressure is maintained at a consistent pressure.

23. The apparatus of claim 20 wherein the pressure-compensation feedback system dynamically adjusts an output pressure of the positive air flow generator to maintain the positive pressure at the predetermined value.

24. The apparatus of claim 23 wherein the pressure-compensation feedback system maintains a peak pressure.

25. The apparatus of claim 20 wherein the pressure-compensation feedback system maintains the positive pressure by flowing air from the apparatus.

26. The apparatus of claim 20 wherein the pressure-compensation feedback system dynamically adjusts the positive air flow generator to maintain the positive pressure at the predetermined value.

27. The apparatus of claim 26 wherein the pressure-compensation feedback system dynamically adjusts a speed of the positive air flow generator.

28. The apparatus of claim 26 wherein the pressure-compensation feedback system dynamically adjusts an output pressure of the positive airflow generator.

29. The apparatus of claim 26 wherein the pressure-compensation feedback system dynamically adjusts an output flow of the positive air flow generator.

30. The apparatus of claim 26 wherein the pressure-compensation feedback system dynamically adjusts the positive air flow generator by flowing air from the apparatus.

31. The apparatus of claim 20 wherein the pressure-compensation feedback system continuously varies an output pressure of the positive air flow generator in order to maintain a peak pressure generated by the positive air flow generator at a predetermined value.

32. An apparatus for generating oscillatory air pulses in a bladder positioned about a person comprising:

an oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber; and

a first motor operably connected with the reciprocating diaphragm;

a positive air flow generator operably connected with the oscillatory air flow generator;

a frequency-compensation feedback system operably connected with the oscillatory air flow generator, wherein the frequency-compensation feedback system maintains a frequency of the oscillatory air flow generator at a predetermined value; and

a pressure-compensation feedback system operably connected with the positive air flow generator, wherein the pressure-compensation feedback system maintains a positive pressure at a predetermined value.

33. The apparatus of claim 32 wherein the pressure-compensation feedback system dynamically adjusts the positive air flow generator to maintain a positive pressure generated by the positive air flow generator at a predetermined value.

34. The apparatus of claim 32 wherein the first motor has a shaft mechanically connected to the reciprocating diaphragm.

35. The apparatus of claim 34 wherein rotation of the shaft reciprocates the reciprocating diaphragm in a cycle and each cycle of the reciprocating diaphragm displaces a fixed volume of air.

36. The apparatus of claim 35 wherein the reciprocating diaphragm causes pressure changes inside the air chamber in comparison to ambient pressure.

37. The apparatus of claim 36 wherein the pressure changes are small in comparison to ambient pressure.

38. The apparatus of claim 36 wherein the pressure changes are less than or equal to about 1 psi.

39. The apparatus of claim 36 wherein a majority of the fixed volume of air is moved into and out of the bladder during each cycle.

40. The apparatus of claim 32 wherein the reciprocating diaphragm comprises a seal extending from the outer periphery of the reciprocating diaphragm to a wall of the air chamber.

41. The apparatus of claim 32 wherein the oscillatory generator further comprises:

a shaft operably connected to the first motor; and

a connecting member operably connecting the shaft to the reciprocating diaphragm.

42. The apparatus of claim 41 wherein the shaft comprises a crankshaft and the connecting member comprises a rod.

43. The apparatus of claim 41 wherein the reciprocating diaphragm comprises a seal generally orthogonal to the connecting member.

44. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

a generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber;

a first motor operably connected with the reciprocating diaphragm; and

wherein the generator provides a positive pressure and an oscillatory pressure;

a frequency-compensation feedback system operably connected with the generator, wherein the frequency-compensation feedback system maintains an oscillation frequency at a predetermined value; and

a pressure-compensation feedback system operably connected with the generator, wherein the pressure-compensation feedback system maintains the positive pressure at a predetermined value.

45. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

a generator comprising an oscillatory air flow generator and a positive air flow generator, the generator providing a positive pressure and an oscillatory pressure;

the oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber; and

a first motor operably connected with the reciprocating diaphragm;

the positive air flow generator operably connected with the oscillatory air flow generator;

a frequency-compensation feedback system operably connected with the generator, wherein the frequency-compensation feedback system maintains an oscillation frequency at a predetermined value; and

a pressure-compensation feedback system operably connected with the generator, wherein the pressure-compensation feedback system maintains the positive pressure at a predetermined value.

46. The apparatus of claim 45 wherein the apparatus loosens and assists expulsion of mucus from lungs of the person.

47. The apparatus of claim 45 wherein the oscillation frequency is independent and higher than a breathing rate of the person.

48. The apparatus of claim 45 wherein the oscillation frequency is between about 5 Hz to about 25 Hz.

49. The apparatus of claim 45 wherein the positive pressure is between about 0.2 psi to about 0.6 psi.

50. The apparatus of claim 45 wherein the positive pressure is a user selected pressure setting.

51. The apparatus of claim 45 wherein the oscillation frequency is a user selected frequency setting.

52. The apparatus of claim 45 wherein the positive pressure is a constant pressure.

53. The apparatus of claim 45 wherein the positive pressure is a consistent pressure.

54. The apparatus of claim 45 wherein the pressure-compensation feedback system maintains a pressure in the bladder above ambient pressure.

55. The apparatus of claim 45 wherein the pressure-compensation feedback system adjusts the positive pressure to allow repeated inhalation and expiration of the person.

56. The apparatus of claim 45 wherein the pressure-compensation feedback system maintains the positive pressure irrespective of repeated inhalation and expiration of the person.

57. The apparatus of claim 45 wherein the pressure-compensation feedback system varies the positive pressure to maintain the positive pressure at the predetermined value.

58. The apparatus of claim 45 wherein the pressure-compensation feedback system detects a peak pressure.

59. The apparatus of claim 45 wherein the pressure-compensation feedback system maintains the positive pressure throughout a range of oscillation frequencies.

60. The apparatus of claim 45 wherein the pressure-compensation feedback system maintains the positive pressure at the predetermined value independent of variations of the bladder.

61. The apparatus of claim 45 wherein the pressure-compensation feedback system detects the positive pressure, compares the positive pressure to a predetermined value, and adjusts the positive pressure to the predetermined value.

62. The apparatus of claim 61 wherein the pressure-compensation feedback system is an electrical feedback system.

63. The apparatus of claim 61 wherein the pressure-compensation feedback system detects the positive pressure using a pressure transducer.

64. The apparatus of claim 61 wherein the predetermined value is a user selected value.

65. The apparatus of claim 61 wherein the pressure-compensation feedback system adjusts the positive pressure by changing an output of the generator.

66. The apparatus of claim 65 wherein a pressure of the output of the generator is reduced.

67. The apparatus of claim 65 wherein a flow of the output of the generator is reduced.

68. The apparatus of claim 67 wherein the flow of the output is reduced by flowing air out of the generator.

69. The apparatus of claim 65 wherein the output of the generator is independent of the oscillation frequency.

70. The apparatus of claim 45 wherein the frequency-compensation feedback system detects the oscillation frequency, compares the oscillation frequency to a predetermined value, and adjusts the oscillation frequency to the predetermined value.

71. The apparatus of claim 70 wherein the frequency-compensation feedback system detects the oscillation frequency by detecting the oscillatory pressure.

72. The apparatus of claim 70 wherein the frequency-compensation feedback system detects the oscillation frequency by detecting the motor speed.

73. The apparatus of claim 70 wherein the frequency-compensation feedback system comprises a pressure transducer.

74. The apparatus of claim of claim 73 wherein the pressure transducer converts air pressure into an oscillating electrical signal.

75. The apparatus of claim 73 wherein the frequency-compensation feedback system provides a voltage level proportional to the oscillation frequency.

76. The apparatus of claim 70 wherein the frequency-compensation feedback system compares the oscillation frequency to a predetermined value by comparing voltages.

77. The apparatus of claim 70 wherein the frequency-compensation feedback system adjusts the oscillation frequency by changing the motor speed.

78. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

a generator comprising an oscillatory air flow generator and a positive air flow generator, the generator providing a positive pressure and an oscillatory pressure;

the oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber; and

a first motor operably connected with the reciprocating diaphragm;

the positive air flow generator operably connected with the oscillatory air flow generator;

a frequency-compensation feedback system operably connected with the generator, wherein the frequency-compensation feedback system maintains an oscillation frequency at a predetermined value; and

wherein the generator maintains the positive pressure at a predetermined value irrespective of the repeated inhalation and expiration of the person.

79. The apparatus of claim 78 wherein the generator dynamically adjusts and controls the positive pressure to allow repeated inhalation and expiration of the person.

80. The apparatus of claim 78 further comprising a control panel, the control panel for user-selection of operating parameters.

81. The apparatus of claim 78 wherein the reciprocating diaphragm comprises a seal extending from the outer periphery of the reciprocating diaphragm to a wall of the air chamber.

82. The apparatus of claim 78 wherein the first motor has a shaft mechanically connected to the reciprocating diaphragm;

wherein rotation of the shaft reciprocates the reciprocating diaphragm in a cycle; and

wherein each cycle of the reciprocating diaphragm displaces a fixed volume of air.

83. The apparatus of claim 82 wherein the reciprocating diaphragm causes pressure changes inside the air chamber in comparison to ambient pressure and wherein a majority of the fixed volume of air is moved into and out of a bladder during each cycle.

84. The apparatus of claim 78 wherein the frequency-compensation feedback system maintains an oscillation frequency at a predetermined value between about 5 Hz to about 25 Hz.

85. The apparatus of claim 78 further comprising a vest comprising a bladder, the vest for placement about a torso of the person, the bladder positioned such that expansions and contractions of the bladder occur generally adjacent to the torso of the person.

86. The apparatus of claim 85 further comprising at least one tube operably connecting the bladder to the generator.

87. The apparatus of claim 85 wherein the bladder causes oscillatory compression of the torso of the person.

88. The apparatus of claim 78 wherein mucus from lungs of the person is loosened and expulsion of the mucus is assisted.

89. The apparatus of claim 85 wherein treatment is initiated by placing the vest around the torso of the person and selecting operating parameters on a control panel without further interaction required by the person with the apparatus during treatment.

90. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

a generator comprising a control panel, an oscillatory air flow generator and a positive air flow generator;

the control panel for user-selection of operating parameters;

the generator providing a positive pressure and an oscillatory pressure, the positive pressure above ambient pressure;

the oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber, the reciprocating diaphragm comprising a seal extending from the outer periphery of the reciprocating diaphragm to a wall of the air chamber; and

a first motor operably connected with the reciprocating diaphragm;

wherein the first motor has a shaft mechanically connected to the reciprocating diaphragm;

wherein rotation of the shaft reciprocates the reciprocating diaphragm in a cycle;

wherein each cycle of the reciprocating diaphragm displaces a fixed volume of air;

wherein the reciprocating diaphragm causes pressure changes inside the air chamber in comparison to ambient pressure;

wherein a majority of the fixed volume of air is moved into and out of the bladder during each cycle;

the positive air flow generator operably connected with the oscillatory air flow generator;

a frequency-compensation feedback system operably connected with the generator, wherein the frequency-compensation feedback system maintains an oscillation frequency at a predetermined value between about 5 Hz to about 25 Hz;

wherein the generator dynamically adjusts and controls the positive pressure to allow repeated inhalation and expiration of the person;

wherein the generator dynamically adjusts and controls the positive pressure to maintain the positive pressure at a predetermined value irrespective of the repeated inhalation and expiration of the person;

a vest comprising a bladder, the vest for placement around a torso of the person, the bladder positioned such that expansions and contractions of the bladder occur generally adjacent to torso of the person;

at least one tube operably connecting the bladder to the generator;

wherein the bladder causes oscillatory compression of the torso of the person;

wherein mucus from lungs of the person is loosened and expulsion of the mucus is assisted; and

wherein treatment is initiated by placing the vest around the torso of the person and selecting operating parameters on the control panel without further interaction required by the person with the apparatus during treatment.

91. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

a generator comprising an oscillatory air flow generator and a positive air flow generator, the generator providing a positive pressure and an oscillatory pressure;

the oscillatory air flow generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber; and

a first motor operably connected with the reciprocating diaphragm;

the positive air flow generator operably connected with the oscillatory air flow generator;

wherein the oscillatory pressure has an oscillation frequency, wherein the generator controls the oscillation frequency; and

wherein the generator maintains the positive pressure at a predetermined value irrespective of the repeated inhalation and expiration of the person.

92. The apparatus of claim 91 further comprising a frequency-compensation feedback system operably connected with the generator, wherein the frequency-compensation feedback system maintains the oscillation frequency at the predetermined value.

93. The apparatus of claim 91 wherein the generator maintains the oscillation frequency at a predetermined value.

94. The apparatus of claim 93 wherein the generator detects the oscillation frequency, compares the oscillation frequency to the predetermined value, and adjusts the oscillation frequency to the predetermined value.

95. The apparatus of claim 94 wherein the generator detects the oscillation frequency by detecting the oscillatory pressure.

96. The apparatus of claim 94 wherein the generator detects the oscillation frequency by detecting a motor speed.

97. The apparatus of claim 94 wherein the generator adjusts the oscillation frequency by changing a motor speed.

98. The apparatus of claim 92 wherein the generator maintains the oscillation frequency at a predetermined value irrespective of the repeated inhalation and expiration of the person.

99. The apparatus of claim 91 wherein the first motor maintains a constant speed irrespective of the repeated inhalation and expiration of the person.

100. The apparatus of claim 91 wherein the generator dynamically adjusts and controls the positive pressure to allow repeated inhalation and expiration of the person; and

wherein the generator dynamically adjusts and controls the positive pressure to maintain the positive pressure at a predetermined value irrespective of the repeated inhalation and expiration of the person.

101. A method for generating oscillatory air pulses in a bladder positioned about a person, comprising:

providing a generator comprising:

an air chamber;

a reciprocating diaphragm operably connected with the air chamber; and

a first motor operably connected with the reciprocating diaphragm;

generating an oscillatory air pressure and a positive air pressure with the generator, the oscillatory air pressure having an oscillation frequency;

maintaining the oscillation frequency with the generator to a first predetermined value;

maintaining the positive air pressure with the generator to allow repeated inhalation and expiration of the person; and

maintaining the positive air pressure with the generator to a second predetermined value irrespective of the repeated inhalation and expiration of the person.

102. The method of claim 101 further comprising dynamically adjusting the oscillation frequency with the generator to the first predetermined value.

103. The method of claim 101 further comprising dynamically adjusting the positive air pressure with the generator to allow repeated inhalation and expiration of the person.

104. The method of claim 101 further comprising dynamically adjusting the positive air pressure with the generator to the second predetermined value irrespective of the repeated inhalation and expiration of the person.

105. The method of claim 101 wherein maintaining the oscillation frequency with the generator to the first predetermined value comprises detecting the oscillation frequency and adjusting the oscillation frequency to approximately equal the first predetermined value.

106. The method of claim 105 wherein detecting the oscillation frequency comprises detecting the oscillatory air pressure.

107. The method of claim 101 wherein maintaining the positive air pressure with the generator to the second predetermined value irrespective of the repeated inhalation and expiration of the person comprises detecting the positive air pressure and adjusting the positive air pressure to approximately equal the second predetermined value.

108. The method of claim 101 further comprising selectively adjusting the first predetermined value.

109. The method of claim 101 further comprising selectively adjusting the second predetermined value.

110. The method of claim 101 further comprising selecting operating parameters with a control panel.

111. The method of claim 101 further comprising:

providing the first motor with a shaft mechanically connected to the reciprocating diaphragm;

rotating the shaft;

reciprocating the reciprocating diaphragm in a cycle; and

displacing a fixed volume of air each cycle.

112. The method of claim 111 further comprising:

changing an air pressure inside the air chamber in comparison to ambient pressure, and

moving a majority of the fixed volume of air into and out of the bladder during each cycle.

113. The method of claim 112 wherein the air pressure inside the chamber is changed less than or equal to 1 psi.

114. The method of claim 101 wherein maintaining the oscillation frequency with the generator to a first predetermined value comprises maintaining the oscillation frequency at a predetermined value between about 5 Hz to about 25 Hz.

115. The method of claim 101 further comprising:

providing a vest comprising a bladder, placing the vest around a torso of the person; and

positioning the bladder and the vest such that expansions and contractions of the bladder occur generally adjacent to the torso of the person.

116. The method of claim 115 further comprising causing oscillatory compression of the torso of the person with the bladder.

117. The method of claim 101 further comprising loosening and assisting the expulsion of mucus from a lung of the person.

118. The method of claim 101 further comprising:

placing a vest around a torso of the person; and

selecting operating parameters on a control panel without further interaction required by the person with the generator.

119. The method of claim 101 wherein the generator further comprises an oscillatory air flow generator and a positive air flow generator, the positive air flow generator operably connected with the oscillatory air flow generator.

REMARKS

Claims 1-119 are pending in the above-identified reissue application, claims 13-119 having been added by this reissue amendment.

Pursuant to 37 C.F.R. § 1.173(c), the following is a statement as to the status of all patent claims and all added claims.

Claims 1-12 were present in the originally-issued patent and are currently pending in the reissued application. Claim 1 is amended; claims 2-12 are unchanged from the originally-issued patent. Claims 13-119 have been added in this reissue application and are presented in this reissue amendment.

Pursuant to 37 C.F.R. § 1.173(c), the following is an explanation as to the support in the disclosure for any concurrently made changes to the claims.

Claim 1 is amended to change the following: The reference to "the positive air flow generator" to read the continuous air flow generator. The reference to "the frequency" is changed to "a frequency." The reference to "the peak pressure" is changed to "a peak pressure."

This claim is supported by the specification as filed and introduces no new matter.

The following discussion indicates the existence of support for the newly added reissue claims. Reference to the specification is reference to the originally-filed specification submitted with the original application.

Claim 13 is substantially similar to claim 1, except that it recites a "positive air flow generator" in place of each instance of "continuous air flow generator." Support for this change is found at page 6, line 6 of the originally filed specification, which recites "positive air

flow generator 16." This feature is also shown in Figure 3, which depicts a block diagram of generator 4.

Claim 14 is substantially similar to claim 13, except that it recites the second feedback and control means as "dynamically adjusting an output pressure of the positive air flow generator." Support for this limitation is found at page 11, lines 5-6 of the originally filed specification, which recite that "positive air flow generator 16 dynamically adjusts the peak pressure in air chamber 17."

Claim 15 recites that the positive pressure is consistent. This limitation is found at page 11, lines 6-7 of the originally filed specification.

Claim 16 recites that the positive pressure is constant. This limitation is found at page 11, lines 10-11 of the originally filed specification.

Claim 17 recites that the second feedback and control means is "for maintaining a positive pressure at a predetermined value." Support for this limitation is found at page 11, lines 4-11 of the original specification.

Claims 18-19 are supported at page 11, lines 6-7 and 10-11 of the original specification; the limitations recited are the same as those of claims 15-16.

Claim 20 recites "a frequency-compensation feedback system operably connected with the oscillatory air flow generator" and a "pressure-compensation feedback system operably connected with the positive air flow generator." Support for these elements is found in Figure 3 and at page 10, lines 12-14 of the original specification.

Claims 21-22 are supported at page 11, lines 6-7 and 10-11 of the original specification; the limitations recited are the same as those of claims 15-16.

Claim 23 recites dynamic adjustment, as supported at page 11, lines 5-6 of the original specification.

Claim 24 recites that "the pressure-compensation feedback system maintains a peak pressure," as supported at page 11, lines 10-11 of the original specification.

Claim 25 recites that "the pressure-compensation feedback system maintains the positive pressure by flowing air from the apparatus." Support for this limitation is found at page 10, line 31 to page 11, line 2 of the specification.

Claim 26 recites that "the pressure-compensation feedback system dynamically adjusts the positive air flow generator to maintain the positive pressure at the predetermined value." Support for this limitation is found at page 11, lines 5-6 of the specification.

Claim 27 recites speed adjustment, as found at page 10, lines 8-10 of the specification.

Claim 28 recites output pressure adjustment, as found at page 10, line 11 of the specification.

Claim 29 recites output flow adjustment, as supported by the specification at page 10, lines 5-7 of the specification.

Claim 30 recites dynamic adjustment by flowing air from the generator. This is supported at page 10, line 31 to page 11, line 2 of the specification.

Claim 31 recites continuous variation of the output pressure. This variation is inherent in the operation of the feedback system as described at page 10, lines 12-28, which recite continuous variation of the voltage output of difference amplifier 52.

Claim 32 is equivalent to claim 20, except that the rod and crankshaft of claim 20 are not included. These features are details of the oscillatory air flow generator, which is described generally at page 6, lines 7-11 of the specification.

Claim 33 recites dynamic adjustment, as in claim 26; support for this limitation is found at page 11, lines 5-6 of the specification.

Claim 34 recites a shaft in connection with the diaphragm. Support for this limitation is found at page 7, line 6 of the specification.

Claim 35 recites rotation of the shaft to reciprocate the reciprocating diaphragm. This is supported by page 7, lines 7-9 of the specification.

Claim 36 recites "the reciprocating diaphragm causes pressure changes inside the air chamber in comparison to ambient pressure." This is supported by page 7, line 10 of the specification.

Claim 37 recites that the pressure changes are relatively small, as recited at page 7, lines 11-12 of the originally filed specification.

Claim 38 recites that the pressure changes are less than 1 psi, as recited at page 7, lines 11-12 of the originally filed specification.

Claim 39 recites that "a majority of the fixed volume of air is moved into and out of the bladder during each cycle." This is supported at page 10, lines 14-15 of the specification.

Claim 40 recites the seal as recited at page 6, line 11 of the original specification.

Claims 41-42 recite the rod and crankshaft assembly as recited at page 7, lines 5-6 of the original specification.

Claim 43 recites the generally orthogonal relationship between the rod and crankshaft, as shown in Figure 3, reference numerals 33 and 34.

Claim 44 is substantially similar to claim 32, except that it recites a single generator providing "a positive pressure" and "an oscillatory pressure." These functions are the same as those of claim 32 and the claim is supported by the same disclosure as is claim 32, as well as at page 2, line 26 of the specification, which refers to "a generator."

Claim 45 is again substantially similar to claim 44, except that the generator is recited as "comprising an oscillatory air flow generator and a positive air flow generator." These functions are again the same as those of claim 32 and the claim is supported by the same disclosure as is claim 32, as well as at page 2, line 26 of the specification.

Claim 46 recites that "the apparatus loosens and assists the expulsion of mucus from lungs of the person." This is supported at page 2, lines 23-24 of the specification.

Claim 47 recites that "the oscillating frequency is independent and higher than a breathing rate of the person." This is supported at page 1, lines 31-32, which describe the general operation of a pneumatic system employing air pulses.

Claim 48 recites that "the oscillating frequency is between about 5 Hz to about 25 Hz." This is supported by the specification at page 5, lines 13-14.

Claim 49 recites that "the positive pressure is between about 0.2 psi to about 0.6 psi." This is supported by the specification at page 5, lines 16-17.

Claim 50 recites a user selected pressure setting. This feature is supported by the original specification at page 5, lines 14-16.

Claim 51 recites a user-selected frequency setting. This feature is supported by the original specification at page 5, lines 12-13.

Claims 52-53 are supported at page 11, lines 6-7 and 10-11 of the original specification; the limitations recited are the same as those of claims 15-16.

Claim 54 recites that the pressure-compensation feedback system maintains a pressure in the bladder above ambient pressure. Pressure above ambient pressure is supported at page 11, lines 6-7 and 10-11 and page 7, lines 10-12 of the original specification.

Claim 55 recites that the pressure-compensation feedback system "adjusts the positive pressure to allow repeated inhalation and expiration of the person." This feature is recited in the specification at page 11, lines 9-10.

Claim 56 recites that the pressure-compensation feedback system "maintains the positive pressure irrespective of repeated inhalation and expiration of the person." This feature is again recited in the specification at page 11, lines 9-10.

Claim 57 recites that the pressure-compensation feedback system "varies the positive pressure to maintain a positive pressure at a predetermined value." This feature is recited at the specification at page 10, line 28; a user-selected value is an example of a predetermined value.

Claim 58 recites detection of a peak pressure. This feature is supported at page 10, line 15 of the specification, which recites "pressure peak detector 51."

Claim 59 recites "maintaining the positive pressure throughout a range of oscillation frequencies." This feature is again recited in the specification at page 11, lines 6-10 and also at page 3 lines 5-7.

Claim 60 recites that "the pressure-compensation feedback system maintains the positive pressure at the predetermined value independent of variations of the bladder." This feature is recited in the specification at page 11, line 9 and page 24 lines 24-27.

Claim 61 recites that "the pressure-compensation feedback system detects the positive pressure, compares the positive pressure to a predetermined value, and adjusts the positive pressure to the predetermined value." The operation of the pressure-compensation feedback system is described at page 10, lines 13-28 of the specification.

Claim 62 recites that "the pressure-compensation feedback system is an electrical feedback system." This electrical feedback system is recited at page 10, lines 13-28 of the specification, which describe the components and function of such an electrical feedback system.

Claim 63 recites a pressure transducer in the feedback system. This is supported by the specification at page 10, line 14, which refers to a "pressure transducer 38."

Claim 64 recites that the predetermined value is a user selected value. This feature is recited by the specification at page 10, line 28, which describes a user selected value.

Claim 65 recites that "the pressure-compensation feedback system adjusts the positive pressure by changing an output of the generator." This is supported by the specification at page 10, lines 8-11.

Claim 66 recites that a pressure of the output of the generator can be reduced. This is supported by the specification at page 10, lines 8-11.

Claim 67 recites that a flow of the output of the generator can be reduced. This is again supported at page 10, lines 8-11 of the specification.

Claim 68 recites reduction of the flow of the output by flowing air out of the generator. This is supported at page 10, line 31 to page 11, line 2 of the specification.

Claim 69 recites that "the output of the generator is independent of the oscillation frequency." This is supported by the original specification at page 8, lines 23-26.

Claim 70 recites a detail of the frequency-compensation feedback system, that "the frequency-compensation feedback system detects the oscillation frequency, compares the oscillation frequency to a predetermined value, and adjusts the oscillation frequency to the predetermined value." This is supported by the original specification at page 8, lines 3-21.

Claim 71 recites a further detail of the frequency-compensation feedback system, that the oscillation frequency is detected by detecting the oscillatory pressure. This is supported by the description of the operation of the pressure transducer 43 at page 8, lines 4-6 of the specification.

Claim 72 recites that the oscillation frequency is detected by detecting the motor speed. This is supported by the specification at page 7, lines 19-24.

Claim 73 recites that the frequency-compensation feedback system comprises a pressure transducer. This is supported by the specification at page 8, line 4, which recites "pressure transducer 43."

Claim 74 recites that "the pressure transducer converts air pressure into an oscillating electrical signal." This is supported by the specification at page 8, lines 4-6, which offer further detail as to the operation of the pressure transducer.

Claim 75 recites that "the frequency-compensation feedback system provides a voltage level proportional to the oscillation frequency." This is supported by the specification at page 8, lines 9-11.

Claim 76 recites that "the frequency-compensation feedback system compares the oscillation frequency to a predetermined value by comparing voltages." This is supported by the specification at page 8, lines 14-16; the comparison is performed by the difference amplifier 46.

Claim 77 recites that "the frequency-compensation feedback system adjusts the oscillation frequency by changing the motor speed." This is supported by the specification at page 8, lines 19-20, describing the operation of the pulse-width modulator 60.

Claim 78 has the generator described as in claim 45, except the pressure-compensation feedback system element is replaced by a "wherein" clause reading: "wherein the generator maintains the positive pressure at a predetermined value irrespective of the repeated inhalation and expiration of the person." The support for the generator is as described for claim 45 above. The support for the clause "wherein the generator maintains the positive pressure at a predetermined value irrespective of the repeated inhalation and expiration of the person" is found at page 11, lines 3-11 of the specification.

Claim 79 adds a second "wherein" clause reading "wherein the generator dynamically adjusts and controls the positive pressure to allow repeated inhalation and expiration of the person." The support for this clause is found at page 10, lines 2-7 of this specification. The term "compensate," used in the specification at page 10, line 6, would be understood by one

of ordinary skill in the art as including dynamic adjustment and control. This is independent of the details of the dynamic adjustment and control or whether it is mechanical, electrical, or a combination thereof.

Claim 80 recites the control panel. Support for the control panel is found at page 5, lines 10-12, which refers to "the control panel 7" and to the ability of the user to select treatment parameters.

Claim 81 recites the reciprocating diaphragm and seal as in claim 40. Support for this claim is as in claim 40.

Claim 82 recites the shaft of the first motor, the mechanical connection of the shaft to the reciprocating diaphragm, and the displacement of a fixed volume of air by each cycle of the reciprocating diaphragm. These details are supported by the specification at page 7, lines 5-9.

Claim 83 recites "wherein the reciprocating diaphragm causes pressure changes inside the air chamber in comparison to ambient pressure and wherein a majority of the fixed volume of air is moved into and out of a bladder during each cycle." These features are recited at page 7, lines 5-18 of the specification.

Claim 84 recites that "the oscillating frequency is between about 5 Hz to about 25 Hz." This is supported by the specification at page 5, lines 13-14.

Claim 85 recites a vest comprising a bladder. This arrangement is supported by the specification at page 2, lines 24-25.

Claim 86 recites "at least one tube operably connecting the bladder to the generator." The recitation of the tube is supported by the specification at page 2, line 26.

Claim 87 recites that the bladder causes oscillatory compression of the torso of the person. This is supported by the specification at page 4, line 29.

Claim 88 recites that mucus from lungs of the person is loosened and expulsion of the mucus is assisted. This function of the device is supported by the specification at page 4, lines 30-31.

Claim 89, describing initiation of treatment and the lack of further interaction between the apparatus and the patient, is supported by the specification at page 11, line 28, to page 12, line 2.

Claim 90 recites various features recited in claims 78-89 and supported by the specification as for those claims, together with the limitation that the reciprocating diaphragm causes pressure changes inside the air chamber in comparison to ambient pressure. This limitation is supported by the specification at page 7 lines 10-12.

Claim 91 is substantially equivalent to claim 78, except that the frequency-compensation feedback system element is replaced with "wherein the oscillatory pressure has an oscillation frequency, wherein the generator controls the oscillation frequency." The control of the oscillation frequency by the generator in the operation of the device is described at page 5, lines 4-5.

Claim 92 recites a frequency-compensation feedback system operably connected with the generator to maintain the oscillation frequency at the predetermined value. The operable connection between the frequency-compensation feedback system and the generator is shown in Figure 3. The maintenance of the oscillation frequency at the predetermined value is supported by the specification at page 9, lines 17-19.

Claim 93 recites the maintenance of the oscillation frequency at a predetermined value by the generator. The maintenance of the oscillation frequency by the generator in the operation of the device is described at page 5, lines 4-5 and page 9, lines 17-19.

Claim 94 recites the detection of the oscillation frequency, the comparison of the oscillation frequency to the predetermined value, and the adjustment of the oscillation frequency to the predetermined value. This is supported by the specification at page 8, lines 9-21.

Claim 95 recites the detection of the oscillatory pressure. This is supported by the specification at page 8, lines 3-9; the pressure transducer 43 detects the oscillatory pressure.

Claim 96 recites the detection of the motor speed. This is supported by the specification at page 7, lines 19-24.

Claim 97 recites the changing of the motor speed. This is again supported by the specification at page 7, lines 19-24 and page 8, line 20.

Claim 98 recites that the generator maintains the oscillation frequency at a predetermined value irrespective of the repeated inhalation and expiration of the person. This is supported by the specification at page 9, lines 17-19.

Claim 99 recites that the first motor maintains a constant speed irrespective of the repeated inhalation and expiration of the person. This is supported by the specification at page 9, lines 17-19.

Claim 100, dependent on claim 91, further recites the "wherein" clauses of claim 90 and is supported as is described above for claim 90.

Claims 101-119 are method claims.

The method of claim 101 is substantially the method of use of the device of claim 91.

The method of claim 102 further recites dynamic adjustment of the oscillation frequency. This is supported by the specification at page 8, lines 10-21.

The methods of claim 103-104 further recite dynamic adjustment of the positive pressure. This is supported by the specification at page 10, lines 12-28.

The method of claim 105 further recites detecting and adjusting the oscillation frequency. This is supported by the specification at page 8, lines 9-21.

The method of claim 106 further recites detection of the oscillatory air pressure. This is supported by the specification at page 8, lines 3-5.

The method of claim 107 further recites detection and adjustment of the positive air pressure. This is supported by the specification at page 10, lines 12-19.

The methods of claim 108-110 further recite selective adjustment of the first and second predetermined values, as indicated by the specification at page 5, lines 12-16.

The method of claim 110 further recites the use of the control panel. This is supported by the specification at page 5, lines 10-17.

The method of claim 111 further recites a method for displacement of a fixed volume of air each cycle. This is supported by the specification at page 7, lines 5-9.

The method of claim 112 further recites changing an air pressure inside the air chamber in comparison to ambient pressure, and moving a majority of the fixed volume of air into and out of the bladder during each cycle. This is supported by the specification at page 7, lines 10-15.

The method of claim 113 recites that the change of air pressure is less than or equal to about 1 psi. This is supported by the specification at page 7, lines 11-12.

The method of claim 114 further recites that the oscillation frequency is maintained at a predetermined value between about 5 Hz to about 25 Hz. This is supported by the specification at page 5, lines 13-14.

The method of claim 115 further recites providing a vest comprising a bladder, placing the vest around a torso of the person; and positioning the bladder and the vest such that expansions and contractions of the bladder occur generally adjacent to the torso of the person. This is supported by the specification at page 4, lines 22-28.

The method of claim 116 further recites causing oscillatory compression of the torso of the person with the bladder. This is supported by the specification at page 4, lines 28-29.

The method of claim 117 further recites loosening and assisting the expulsion of mucus from a lung of the person. This is supported by the specification at page 4, lines 30-31.

The method of claim 118 further recites placing a vest around a torso of the person and selecting operating parameters on a control panel without further interaction required by the person with the generator. This is supported by the specification at page 11, line 28 to page 12, line 2.

The method of claim 119 further recites an oscillatory air flow generator and a positive air flow generator, the positive air flow generator operably connected with the oscillatory air flow generator. This is supported by the specification at page 6, lines 5-8; the operable connection of the positive air flow generator and the oscillatory air flow generator is shown in Figure 3.

In general, claims 13-119 are added to address aspects of the invention that were not previously claimed, although described in detail in the specification and part of what the inventors considered to be their invention.

Claim 13 is substantially equivalent to issued claim 1 except that the term "continuous air flow generator" is replaced by <u>positive air flow generator</u>, and the description of the second feedback and control means, which controls the positive air flow generator, is modified accordingly.

Claim 14 is similar to claim 13, except in the description of the second feedback and control means. In claim 14, the second feedback and control means is described as "dynamically adjusting an output pressure of the positive air flow generator," while in claim 13, the second feedback and control means is described as "continuously varying an output pressure of the positive air flow generator."

Claim 17 is similar to claim 14, except that the second feedback and control means is "for maintaining a positive pressure at a predetermined value." There is no reference to "dynamically adjusting."

Claim 20 eliminates the "means" language and refers to "a frequency-compensation feedback system operably connected with the oscillatory air flow generator" and a "pressure-compensation feedback system operably connected with the positive air flow generator."

Dependent claims 21-31 add features related to the pressure-compensation feedback system.

Claim 32 removes the rod and crankshaft from claim 20. The specification makes it clear that the rod and crankshaft are details represent a way of carrying out the function of the device.

Dependent claims 34-43 add features related to the motor-diaphragm connection and seal.

Claim 44 adds a generic term "generator" replacing both the "oscillatory air generator" and "positive air generator." The generator is recited as providing both a "positive pressure" and an "oscillatory pressure."

Claim 45 is similar to claim 44, except that it refers to the "generator" comprising "an oscillatory air flow generator" and "a positive air flow generator."

Dependent claims 46-53 add further features from the specification.

Dependent claims 54-69 add features related to the pressure-compensation feedback system.

Dependent claims 70-77 add features related to the frequency-compensation feedback system.

Claim 78 broadens the description of the generator in accord with the specification while maintaining the recitation of the frequency-compensation feedback system.

Claims 79-89 are dependent claims that add various features of the device.

Claim 90 is a detailed claim reciting various features of the device.

Claim 91 is an independent claim that is similar to claim 78 but replaces the frequency-compensation feedback system element with a wherein clause.

Claims 92-100 are dependent claims that add various features of the device of claim 91.

As indicated above, claims 101-119 are method claims that highlight the modes of operation and features of the device, including the use of the control panel, the incorporation of the device into a vest to be placed over the torso of a user, and the operation of the device without further interaction with the user once the desired oscillatory frequency and peak pressure are set.

Examination of the claims pending in the above-identified reissue application and allowance of these claims are respectfully requested.

Respectfully submitted,

Dated: January 14, 2002

Michael B. Farber
Registration No. 32,612

OPPENHEIMER WOLFF & DONNELLY LLP
2029 Century Park East, 38th Floor
Los Angeles, California 90067-3024
(310) 788-5104

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	)))))))))	Case Number: _______ **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

Plaintiff American Biosystems, Inc. ("American Biosystems"), for its Complaint for Patent Infringement against Defendant Electromed, Inc. ("Electromed") states and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action by American Biosystems to enforce United States Patent 6,036,662 which is being infringed by Electromed. American Biosystems is a Minnesota corporation that manufactures and distributes innovative oscillatory chest compression devices throughout the United States. These devices represent a major advancement in the treatment of numerous respiratory disorders, and specifically, cystic fibrosis. American Biosystems owns a patent covering this technology which generally relates to a device including a vest with a bladder that is inflated with air to suitable pressure. A diaphragm is then used to oscillate the pressure in the vest causing pulses or blows to the chest cavity thereby loosening, and assisting in the expulsion of, secretions in a person's lungs.

2. Electromed also manufacturers and distributes chest compression devices throughout the United States. American Biosystems' sales of its devices compete directly with Electromed's sales. Although Electromed has no license or other right to use American Biosystem's patented technology, Electromed has introduced a device utilizing the same type of

oscillatory pressure system that is the subject of the '662 Patent. As alleged in more detail in this complaint, Electromed's product infringes American Biosystems.

PARTIES, JURISDICTION AND VENUE

3. American Biosystems is a corporation organized and existing under the laws of Minnesota with its principal place of business in St. Paul, Minnesota.

4. Electromed is a corporation organized and existing under the laws of Minnesota with its principal place of business in Minnetonka, Minnesota.

5. This is a claim of patent infringement arising under 35 U.S.C. §§ 271 and 281, 283-85.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1400(b) because Electromed resides in this district, because a substantial part of the conduct giving rise to American Biosystems' claims occurred in this district, and because Electromed has committed acts of infringement in this district.

GENERAL ALLEGATIONS

A. The Patent In Issue.

8. On March 14, 2000, the United States Patent and Trademark Office duly and legally issued United States Patent No. 6,036,662, which claims an apparatus for generating oscillatory air pulses in a bladder positioned about a person. The '662 Patent issued to American Biosystems as assignee of the inventors Nicholas P. Van Brunt and Donald J. Gagne. A true and correct copy of the '662 Patent is attached hereto as Exhibit A. American Biosystems is the owner of the entire right, title and interest in and to the '662 Patent.

B. Electromed's Infringing Product.

10. Electromed is the manufacturer of the Medpulse™ Respiratory Vest system. The system includes an inflatable vest and a portable air pulse generator which provides oscillatory air pressure for loosening and assisting in the expulsion of secretions in a person's lungs.

C. Claim for Patent Infringement.

11. Electromed is directly infringing claims of the '662 Patent by making, offering to sell and selling chest compression devices with oscillatory air pressure and feedback system controls for controlling the pressure exerted on the body.

12. Electromed is actively inducing infringement of claims of the '662 Patent by others, in that Electromed is intentionally aiding and abetting others to infringe claims of the patent, including by offering products which have no substantial non-infringing use or purpose. On information and belief, Electromed's devices have been used by others and such use is direct infringement.

13. American Biosystems has been damaged by Electromed's infringement of the American Biosystems' patent and will continue to be damaged and irreparably harmed in the future unless Electromed is enjoined from infringing the patents.

14. On information and belief, Electromed has infringed the American Biosystems' patent willfully at all times. Electromed will have had actual knowledge of the '662 Patent at least since the time of service of this complaint and its continuing infringement is willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, American Biosystems prays for the following relief:

1. A judgment that Electromed has infringed United States Patent No. 6,036,662;

2. Preliminary and permanent injunctions enjoining and restraining Electromed, its officers, directors, agents, servants, employees and all others acting under or through it, directly or indirectly, from infringing United States Patent No. 6,036,662.

3. A judgment requiring Electromed to pay damages under 35 U.S.C. § 284, including a judgment that infringement has been willful, along with trebling of damages, with interest;

4. A judgment requiring Electromed to pay the costs and disbursements of this action and attorney's fees as provided by 35 U.S.C. § 285, with interest; and

5. Such other and further relief as the Court may deem just and equitable.

Date: December 6, 2000

OPPENHEIMER WOLFF & DONNELLY LLP

By ______________________

Jacob M. Holdreith, #211011
Cyrus A. Morton, #287325
3400 Plaza VII Building
45 South 7th Street
Minneapolis, MN 55402
Phone: (612) 607-7000
Fax No.: (612) 607-7100

ATTORNEYS FOR PLAINTIFF

US006036662A

United States Patent [19]

Van Brunt et al.

[11] **Patent Number: 6,036,662**

[45] **Date of Patent: *Mar. 14, 2000**

[54] **OSCILLATORY CHEST COMPRESSION DEVICE**

[75] Inventors: **Nicholas P. Van Brunt**, White Bear Lake; **Donald J. Gagne**, St. Paul, both of Minn.

[73] Assignee: **American Biosystems, Inc.**, St. Paul, Minn.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **09/039,606**

[22] Filed: **Mar. 16, 1998**

Related U.S. Application Data

[63] Continuation of application No. 08/661,931, Jun. 11, 1996, Pat. No. 5,769,797.

[51] **Int. Cl.**^{7} A61H 31/00

[52] **U.S. Cl.** 601/41; 601/44; 601/152

[58] **Field of Search** 601/41–44, 48, 601/55, 56, 77, 148–152; 128/DIG. 20; 602/13

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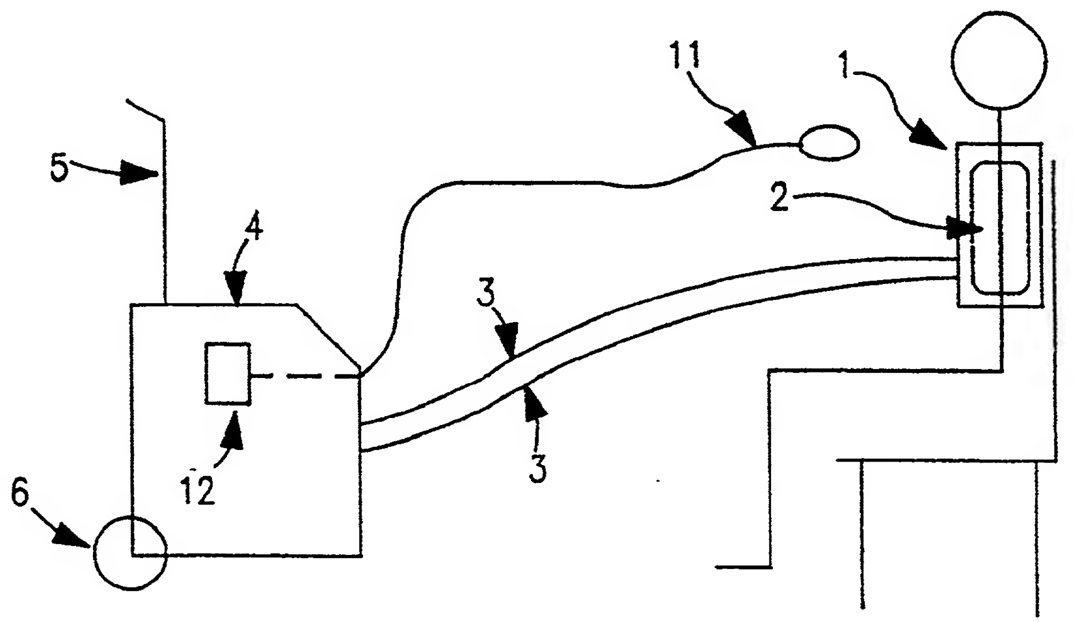
Primary Examiner—Danton D. DeMille
Attorney, Agent, or Firm—David B. Edgeworth

[57] **ABSTRACT**

An oscillatory chest compression device includes an oscillatory air flow generator and a positive air flow generator. A first feedback system controls the oscillation rate of the oscillatory air flow generator, and a second feedback system controls the peak pressure created by the positive air flow generator.

12 Claims, 3 Drawing Sheets



EX. A

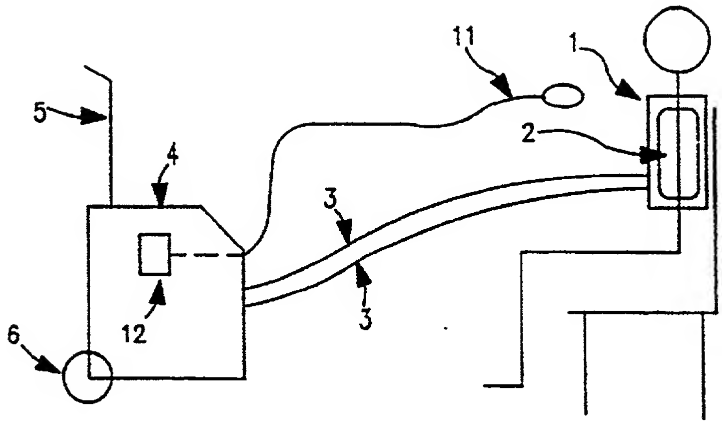


FIG. 1

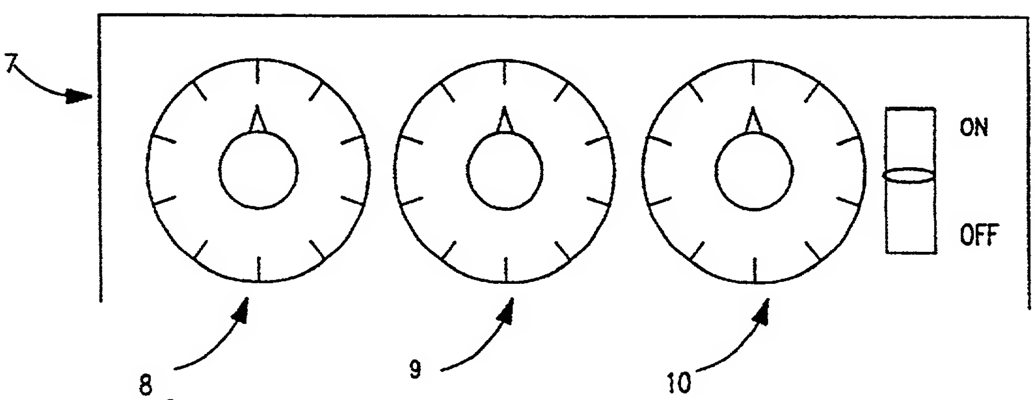


FIG. 2

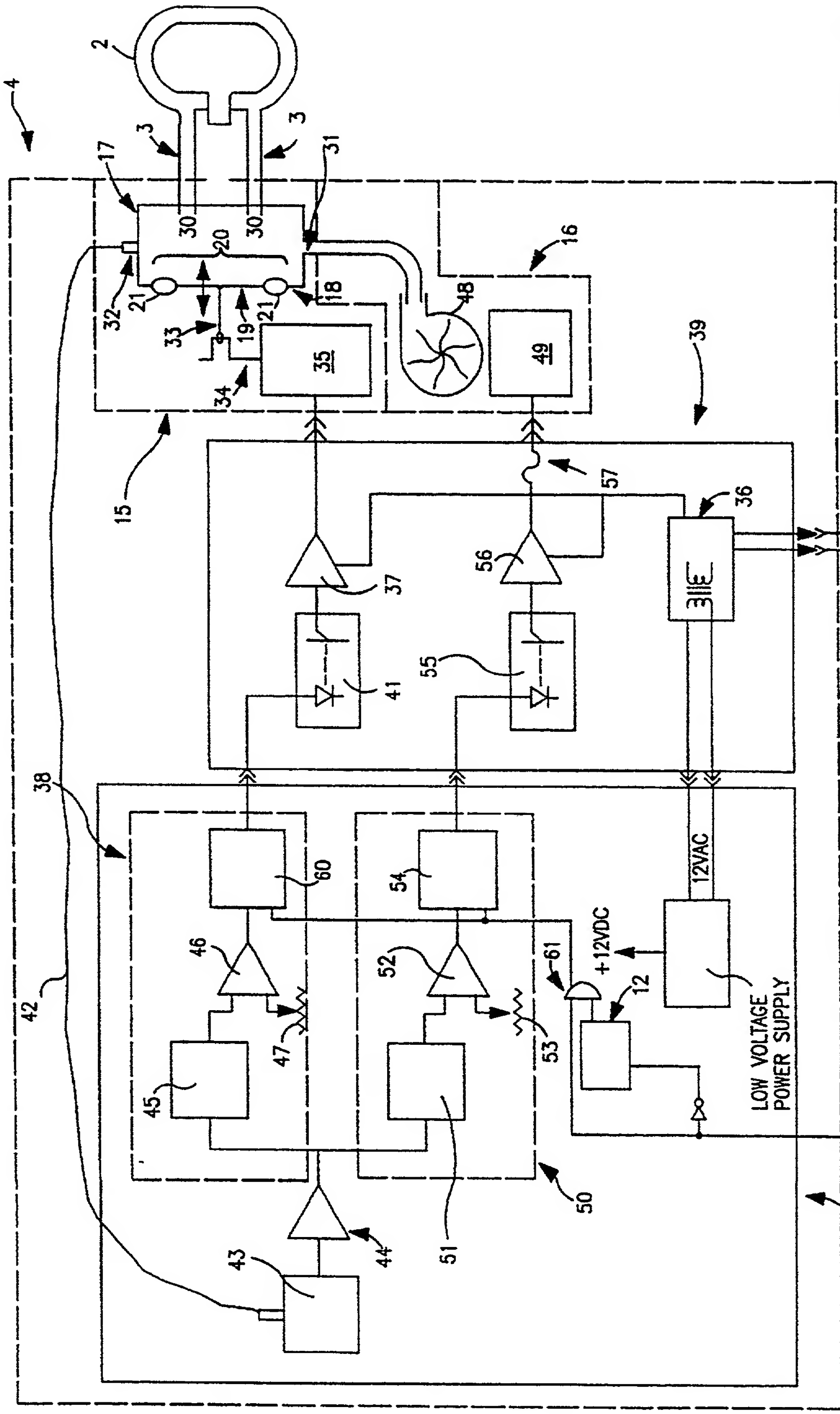


FIG. 3

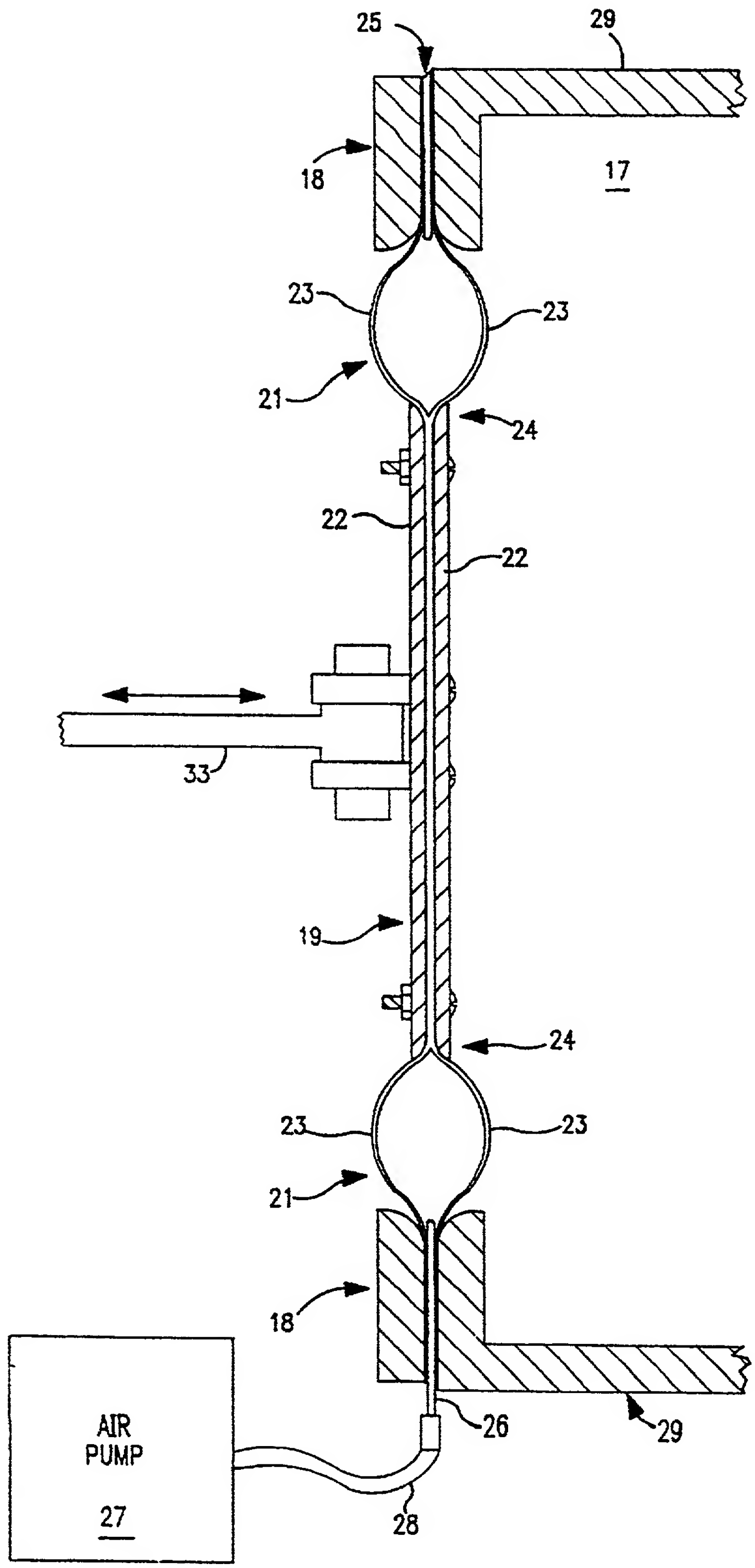


FIG. 4

OSCILLATORY CHEST COMPRESSION DEVICE

This is a continuation of application Ser. No. 08/661,931, filed Jun. 11, 1996, now U.S. Pat. No. 5,769,797.

FIELD OF THE INVENTION

The present invention relates to an oscillatory chest compression device.

BACKGROUND OF THE INVENTION

Certain respiratory disorders, such as cystic fibrosis, emphysema, asthma, and chronic bronchitis, may cause mucous and other secretions to build up in a person's lungs. It is desirable, and sometimes essential, that the secretion build-up be substantially removed from the lungs to enable improved breathing. For example, Cystic fibrosis is an hereditary disease that affects the mucous secreting glands of a person, causing an excessive production of mucous. The mucous fills in the person's lungs and must be reduced daily to prevent infection and enable respiration by the person.

Currently there is no cure for cystic fibrosis. Current treatment of cystic fibrosis includes an aerosol therapy to assist lung drainage and repeated pounding on the upper torso of the person to loosen and expel the mucous. This daily treatment may take several hours and requires a trained individual to apply the pounding treatment.

Pneumatic and mechanical systems have been developed for loosening and removing secretions from a person's lungs. In one pneumatic system, a bladder is positioned around the upper torso of the patient. One or more hoses connect the bladder with a mechanism for generating air pulses in the bladder. The pulsing of the bladder provides chest compressions to the patient. The pulsing frequency is independent of and higher than the patient's breathing rate. One such system, disclosed in U.S. Pat. No. 4,838,263, is a valve-operated, open-loop system that requires the patient to interact with the system throughout the treatment period.

Other systems include mechanical vibrators. Some vibrator systems are attached to the person's torso, while others are hand-held. Vibrators and other direct mechanical compression devices are likely to be heavier than pneumatic compression devices.

A chest compression device, as is the case with medical devices generally, must meet a variety of requirements. First, the chest compression device must be safe to operate. The patient receiving treatment should not be able to adjust the device to create unsafe treatment conditions. Failure of device components must not create unsafe conditions. The chest compression device should provide some user control, allowing the device to be customized to the needs of individual users. The device should be easy to understand and operate by the user; detailed training and complicated controls increase the cost of the treatment. Finally, the device should minimize intrusion into the daily activities of the user.

SUMMARY OF THE INVENTION

The present invention is directed to an oscillatory chest compression device that loosens and assists in expulsion of secretions in a person's lungs. A vest, containing a bladder, is secured to a patient's upper torso. One or more tubes connect the bladder with a generator. The generator includes a first, oscillatory air flow generator. A second, positive air flow generator is operably connected with the oscillatory air flow generator. Feedback systems control both the oscillatory air flow generator and the positive air flow generator, providing treatment at user-selected parameters and preventing unsafe conditions.

The inventors of the present invention were the first to recognize several design aspects that result in an efficacious, safe, and easy-to-use oscillatory chest compression device. The oscillatory air flow generator includes a reciprocating diaphragm. The reciprocating diaphragm delivers a generally constant pressure throughout the range of oscillation frequencies, providing efficacious treatment throughout the range of user-selectable frequency settings. The reciprocating diaphragm provides a more efficient transfer of electrical energy to pneumatic energy as compared to prior rotary-valve designs.

One major safety concern in a pneumatic chest compression device is over-pressurization of the bladder. The reciprocating diaphragm provides inherently safe pressure conditions. The only way a reciprocating diaphragm can increase pressure in the bladder is to increase the diaphragm stroke length or diameter. However, there is no failure mode that will increase the stroke length or diameter of the reciprocating diaphragm.

The present invention includes a positive air flow generator operably connected with the oscillatory air flow generator. The positive air flow generator compensates for any leakage in the system, including the hoses and bladder. Also, the positive air flow generator, in connection with a feedback system, maintains the desired peak pressure delivered by the bladder, independent of variations in the bladder and the patient. The positive air flow generator includes the safety feature of a fuse connected with the input power. The fuse is rated so as to prevent a power surge from causing the positive air flow generator to generate an unsafe, high pressure.

The oscillatory chest compression device of the present invention is automated, allowing the user to select operating parameters for a treatment and then direct his attention to other matters. The feedback systems of the present invention maintain the user-selected parameters during the treatment. The user controls are selected so that the user cannot select operating parameters that would result in unsafe chest compression treatment.

Other advantages and features will become apparent from the following description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects of the present invention will be described in detail with respect to the accompanying drawings, in which:

FIG. 1 is an illustration of a person and a chest compression device;

FIG. 2 is a schematic diagram of the control panel of a chest compression device;

FIG. 3 is a schematic diagram of a chest compression device; and

FIG. 4 is a schematic diagram of a portion of a chest compression device.

DETAILED DESCRIPTION OF THE EMBODIMENTS

A chest compression device is shown in FIG. 1. A vest 1 is secured about the torso of a patient. A bladder 2 is fitted within vest 1. Oscillatory air pulses are delivered to bladder 2. The outer surface of vest 1 is made of a non-stretch

material, causing the expansions and contractions of bladder 2 to occur generally adjacent the patient's torso. The expansions and contractions create a pneumatic, oscillatory compression of the patient's torso to loosen and assist the expulsion of mucous and other secretions in the patient's lungs. Suitable vests are available from American Biosystems, Inc., St. Paul, Minn., the assignee of the present invention.

Tubes 3 connect bladder 2 with generator 4. Two tubes 3 are shown in FIGS. 1 and 3; however, the number of tubes 3 may be varied depending on the desired operating parameters of bladder 2. Generator 4 generates oscillatory air pulses in accordance with user-selected settings. The pulses are converted into compressions of the patient's torso by bladder 2. Generator 4 may be configured as a mobile unit with handle 5 and wheels 6, or as a stationary unit.

Generator 4 includes a control panel 7, shown in FIG. 2. Timer 8 allows the user to select a treatment period. Frequency selector 9 allows the user to select the frequency of compressions. In one embodiment, the frequency range is about five to twenty-five Hz. Pressure selector 10 allows the user to select the peak pressure for each oscillation. In one embodiment, the pressure range is about 0.2 to 0.6 PSI.

As shown in FIG. 1, the user typically is seated during treatment. However, the user has some local mobility about generator 4, determined by the length of hoses 3. Also, the mobile unit shown in FIG. 1 may be easily transferred to different locations. For treatment, the user selects the desired operating parameters and no further interaction by the user is required; generator 4 maintains the user-selected parameters. The user may change the settings at any time. A remotely-operated control 11 allows the user to start and stop the treatment.

Generator 4 also includes a ten-minute safety timer 12. Once the user initiates treatment, safety timer 12 starts. Safety timer 12 is reset each time the user activates start/stop control 11. If the safety timer expires, generator 4 is turned off. Therefore, even if the user loses consciousness or is otherwise incapacitated, generator 4 is turned off after a predetermined period, reducing the likelihood of injury to the user due to an excessive period of chest compressions.

A block diagram of generator 4 is shown in FIG. 3. Generator 4 includes two air flow units, oscillatory air flow generator 15 and positive air flow generator 16. Oscillatory air pulses are generated by oscillatory air flow generator 15. Oscillatory air flow generator 15 includes an air chamber 17. Air chamber 17 includes a wall 18 having a reciprocating diaphragm 19 suspended in an aperture 20 of wall 18 by a seal 21.

As shown in FIG. 4, diaphragm 19 is a generally rigid disk assembly of two opposed, generally circular disks 22. Flexible, air-tight seal 21 is formed by two rubber disks 23 positioned between diaphragm disks 22. Diaphragm disks 22 are clamped together by bolts or other fastening means. Rubber disks 23 extend from the outer periphery 24 of diaphragm disks 22 into a groove 25 in wall 18, thereby forming a generally air-tight seal in the gap between diaphragm 19 and wall 18.

Air pressure is supplied to seal 21 by capillary tube 26, which is supplied by air pump 27 and tubing 28. Air pump 27 maintains the air pressure in seal 21 higher than the maximum pressure peaks in air chamber 17. In one embodiment, the air pressure in seal 21 is maintained at about 1.5 PSI. The pressure relationship causes rubber disks 23 to maintain the inflated shape as shown in FIG. 4 as diaphragm 19 reciprocates. This results in a smooth, quiet, low-friction travel of diaphragm 19, while maintaining an airtight seal between diaphragm 19 and wall 18.

The remaining walls 29 of air chamber 17 are generally rigid. Apertures 30 provide fluid communication between air chamber 17 and tubes 3. Aperture 31 provides fluid communication with positive air flow generator 16. Aperture 32 provides fluid communication with the control system described below.

Diaphragm 19 is mechanically connected through rod 33 to a crankshaft 34, which is driven by motor 35. Each rotation of crankshaft 34 causes a fixed volume of air (defined by the area of the diaphragm multiplied by the length of the stroke) to be displaced in air chamber 17. The pressure changes inside air chamber 17 resulting from the displacements are relatively small (e.g., less than one PSI) in comparison to the ambient air pressure. Therefore, there is little compression of the air in air chamber 17 and the majority of the displaced air is moved into and out of bladder 2 through tubes 3 during each cycle. This results in the amount of air transferred into and out of bladder 2 during each cycle being largely independent of other factors, such as the oscillation frequency and bladder size.

In one embodiment, motor 35 is a permanent magnet DC brush motor. The motor speed is generally controlled by the voltage supplied to it. A 170 volt DC power supply 36 energizes power amplifier 37. Power amplifier 37 is controlled by a frequency-compensation feedback circuit 38, thereby supplying variable length pulses to motor 35. The inductance of motor 35 effectively smoothes the pulses to a constant power level that is proportional to the ratio of the pulse length divided by the pulse period. Using a pulse period of 20 kHz, the pulse length controls the motor speed.

As shown in FIG. 3, all of the power circuitry is located on power board 39. The control circuitry is located on a separate, low-energy control board 40. The control board 40 is connected to the power board 39 by 5000-volt opto-isolators 41, 55. The high level of isolation between the power board 39 and control board 40 provides significant shock protection for the user.

Conduit 42 conveys changes in pressure from air chamber 17 to pressure transducer 43. Pressure transducer 43 converts the air pressure into an oscillating electronic signal, which is then amplified by amplifier 44. The output of amplifier 44 is then processed by frequency-compensation feedback circuit 38.

Frequency-to-voltage converter 45 converts the oscillating signal to a voltage level proportional to the frequency. The output of converter 45 is fed to difference amplifier 46. Difference amplifier 46 has a second input 47 representing the user-selected frequency setting. Difference amplifier 46 compares the voltage representing the user-selected frequency with the voltage representing the actual frequency detected in air chamber 17. The output of difference amplifier 46 is input into pulse-width modulator 60. The output of pulse-width modulator 60 is fed through opto-isolator 41 and power amplifier 37 to motor 35, thereby adjusting the speed of motor 35 and, consequently, the oscillation frequency in air chamber 17.

Reciprocating diaphragm 19 of oscillatory air flow generator 15 provides several advantages. First, the amount of air transferred into and out of bladder 2 during each cycle is largely independent of the oscillation frequency setting. In prior art systems, using a constant air flow and valve configuration, less air flow was delivered at higher frequencies. Therefore, the present invention provides a more consistent air flow over the user selectable frequency range. This consistency provides a more efficacious treatment.

Further, reciprocating diaphragm 19 is both efficient and safe. The substantially closed-loop reciprocating diaphragm configuration provides a more efficient transfer of electrical energy to pneumatic energy as compared to prior art valve designs. Also, the reciprocating diaphragm provides inherently safe air flow.

One of the main safety concerns with bladder-type chest compression systems is over-inflation of the bladder. In a reciprocating diaphragm system, there is no net increase in pressure, i.e., the air flow on the in-stroke equals the air flow on the out-stroke. The only way to increase air flow is to increase the diaphragm stroke length or the surface area of the diaphragm. In the present invention, there is no failure mode that could cause either an increased stroke length or increased diaphragm surface area. Conversely, in valve-operated pneumatic devices, a malfunction of a valve may cause unsafe pressures to develop in bladder 2.

Frequency-compensation feedback system 38 serves to maintain the oscillation frequency at the user-selected value. Also, frequency selector 9 is calibrated so that oscillatory air flow generator 15 operates at a maximum oscillation rate as the default value, and frequency selector 9 can only decrease the oscillation frequency. The maximum default oscillation rate is selected to be within safe parameters, therefore, the user cannot increase the oscillation rate to an unsafe level.

Although diaphragm 19 approximates a perfect system in terms of displacement of air into and out of bladder 2 on each stroke, remaining parts of the closed system are less perfect. For example, bladder 2 typically leaks air at a variable rate that is difficult to model. The amount of air leakage is influenced by many factors, including variations in production of the bladder, age, use, and other factors.

Also, tubes 3 and the various connections within the system may also leak. Additionally, the air pressure delivered to bladder 2 must be varied due to the repeated inhalation and expiration of the user during treatment, and also due to the size of the particular user. Therefore, positive air pressure generator 16 is used to supply positive air pressure to the system to compensate for the above-identified variables.

Positive air flow generator 16 includes a blower 48 driven by motor 49. The speed of motor 49 is controlled by pressure-compensation feedback system 50, thereby controlling the output pressure of blower 48.

As shown in FIG. 3, pressure-compensation feedback system 50 is similar to frequency-compensation feedback system 38. The output of pressure transducer 43 is fed through amplifier 44 to a pressure peak detector 51. Peak detector 51 captures the pressure waveform peaks within air chamber 17 and generates a voltage proportional to the pressure peak. This voltage is fed to difference amplifier 52.

Difference amplifier 52 includes a second input 53 representing the user-selected pressure. The difference in actual peak pressure and selected peak pressure is represented in the voltage output of difference amplifier 52 and is fed to pulse-width modulator 54. The output of pulse-width modulator 54 is fed through a second opto-isolator 55 and a second power amplifier 56 on power board 39 to motor 49. Motor 49 drives blower 48 to maintain the peak pressure in air chamber 17 at the user-selected value. '

One of ordinary skill in the art will recognize that the pressure in air chamber 17 may also be decreased by a flow of air from air chamber 17 into blower 48, depending on the pressure in air chamber 17 compared to the pressure created by blower 48. In one embodiment, blower 48 may be reversible.

Positive air flow generator 16 and pressure-compensation feedback system 50 provide several advantages. First, positive air flow generator 16 dynamically adjusts the peak pressure in air chamber 17 to provide a consistent peak pressure based on the user selected peak pressure, independent of leaks in the system, size of the user, condition of the bladder, and the repeated inhalation and expiration of the user. Maintaining a constant peak pressure provides for increased efficacy of treatment.

Also, the user only has to make an initial pressure selection, no further interaction with generator 4 is required. The maximum peak pressure setting is selected to be within a safe treatment range. As an additional safety feature, fuse 57 serves to prevent a power surge in power supply 36 from causing blower 48 to inflate bladder 2 to an unsafe pressure.

The circuit for user-operated start/stop control 11 and safety timer 12 are also shown in FIG. 3. In one embodiment, control 11 is a pneumatic switch of known construction. In other embodiments, control 11 may be electronic or electro-mechanical. Actuation of control 11 serves to reset safety timer 12 and also control pulse width modulators 60, 54. The AND gate 61 requires that safety timer 12 be active (i.e., not zero) and control 11 be ON in order for generator 4 to create air pulses.

It is important to note the general ease-of-use provided by the present invention. To initiate treatment, the user simply puts on vest 2 and selects operating parameters on control panel 7, very little training is required. This helps keep down the total cost of the treatment. Also, the user is not required to constantly interact with the device during treatment.

Other embodiments are within the scope of the following claims.

What is claimed is:

1. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator, comprising
 an air chamber;
 a reciprocating diaphragm operably connected with the air chamber,
 a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;
 a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and
 a first motor operably connected with the crankshaft;

a continuous air flow generator operably connected with the oscillatory air flow generator;

a first feedback and control means operably connected with the oscillatory air flow generator for maintaining the frequency of the oscillatory air flow generator at a predetermined value;

and a second feedback and control means operably connected with the continuous air flow generator for continuously varying the output pressure of the continuous air flow generator in order to maintain the peak pressure generated by the positive air flow generator at a predetermined value.

2. The apparatus of claim 1 further comprising means for connecting the oscillatory air flow generator with a bladder.

3. The apparatus of claim 1 wherein the first feedback and control means comprises:

means for detecting the oscillation rate in the air chamber;

means for comparing the oscillation rate with the predetermined value; and

means for adjusting the oscillatory air flow generator so that the detected oscillation rate approximately equals the predetermined value.

4. The apparatus of claim 1 further comprising a frequency selector, allowing a user to select the predetermined frequency.

5. The apparatus of claim 1 wherein the continuous air flow generator comprises a blower, and a second motor operably connected with the blower.

6. The apparatus of claim 5 further comprising means connected to the second motor for preventing the second motor from operating the blower above a predetermined pressure.

7. The apparatus of claim 6 wherein the means for preventing comprises a fuse.

8. The apparatus of claim 1 wherein the second feedback and control means comprises:

means for detecting the peak pressure in the air chamber;

means for comparing the detected peak pressure with the predetermined value; and

means for adjusting the continuous air flow generator so that the detected peak pressure equals the predetermined value.

9. The apparatus of claim 1 further comprising a pressure selector, allowing a user to select the predetermined peak pressure.

10. The apparatus of claim 1, further comprising a remote start/stop control operably connected with the first and second feedback and control means.

11. The apparatus of claim 10 further comprises a timer operably connected with the remote start/stop control.

12. The apparatus of claim 1, further comprising a seal extending from an outer periphery of the diaphragm to a wall of the air chamber, the seal comprising first and second generally opposed disks defining an annular region for receiving air, and a pump operably connected with the annular region, the pump maintaining the air pressure in the annular region greater than the peak pressure generated in the air chamber.

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